

## General

### Guideline Title

Breast cancer follow-up and management after primary treatment: American Society of Clinical Oncology clinical practice guideline update.

### Bibliographic Source(s)

Khatcheressian JL, Hurley P, Bantug E, Esserman LJ, Grunfeld E, Halberg F, Hantel A, Henry NL, Muss HB, Smith TJ, Vogel VG, Wolff AC, Somerfield MR, Davidson NE, American Society of Clinical Oncology. Breast cancer follow-up and management after primary treatment: American Society of Clinical Oncology clinical practice guideline update. J Clin Oncol. 2013 Mar 1;31(7):961-5. [20 references] PubMed

### **Guideline Status**

This is the current release of the guideline.

This guideline updates previous versions: Khatcheressian JL, Wolff AC, Smith TJ, Grunfeld E, Muss HB, Vogel VG, Halberg F, Somerfield MR, Davidson NE, American Society of Clinical Oncology. American Society of Clinical Oncology 2006 update of the breast cancer follow-up and management guidelines in the adjuvant setting. J Clin Oncol 2006 Nov 1;24(31):5091-7. [30 references]

American Society of Clinical Oncology. American Society of Clinical Oncology 1998 update of recommended breast cancer surveillance guidelines. J Clin Oncol 1999 Mar;17(3):1080-2.

American Society of Clinical Oncology. Recommended breast cancer surveillance guidelines. J Clin Oncol 1997 May;15(5):2149-56.

# Recommendations

# Major Recommendations

Recommendations for Breast Cancer Follow-Up and Management in the Adjuvant Setting							
Mode of Surveillance	Recommendation*						
RECOMMENDED							
History/physical examination	All women should have a careful history and physical examination every 3 to 6 months for the first 3 years after primary therapy, then every 6 to 12 months for the next 2 years, and then annually.						
	The history and physical examination should be performed by a physician <sup>†</sup> experienced in the surveillance of patients with cancer and in breast examination.						
Patient education	Physicians should counsel patients about the symptoms of recurrence including new lumps, bone pain, chest pain, dyspnea, abdominal pain, or persistent headaches. Helpful Web sites for patient education include www.cancer.net						

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symptoms of	Recommendations for Breast Cancer Follow-Up and Management in the Adjuvant Setting					
Moderate Surveillance	Recommendation*					
Referral for genetic counseling	Women at high risk for familial breast cancer syndromes should be referred for genetic counseling in accordance with clinical guidelines recommended by the US Preventive Services Task Force. Criteria to recommend referral include the following: Ashkenazi Jewish heritage; history of ovarian cancer at any age in the patient or any first- or second-degree relatives; any first-degree relative with a history of breast cancer diagnosed before the age of 50 years; two or more first-or second-degree relatives diagnosed with breast cancer at any age; patient or relative with diagnosis of bilateral breast cancer; and history of breast cancer in a male relative. ‡					
Breast self- examination	All women should be counseled to perform monthly breast self-examination.					
Mammography	Women treated with breast-conserving therapy should have their first post-treatment mammogram no earlier than 6 months after definitive radiation therapy. Subsequent mammograms should be obtained every 6 to 12 months for surveillance of abnormalities. Mammography should be performed yearly if stability of mammographic findings is achieved after completion of locoregional therapy.					
Pelvic examination	Regular gynecologic follow-up is recommended for all women. Patients who receive tamoxifen therapy are at increased rifer developing endometrial cancer and should be advised to report any vaginal bleeding to their physicians. Longer follow up intervals may be appropriate for women who have had a total hysterectomy and oophorectomy.					
Coordination of care	The risk of breast cancer recurrence continues through 15 years after primary treatment and beyond. Continuity of care for patients with breast cancer is recommended and should be performed by a physician experienced in the surveillance of patients with cancer and in breast examination, including the examination of irradiated breasts. Follow-up by a PCP seems to lead to the same health outcomes as specialist follow-up with good patient satisfaction.  If a patient with early-stage breast cancer (tumor <5 cm and <4 positive nodes) desires follow-up exclusively by a PCP, care may be transferred to the PCP approximately 1 year after diagnosis. If care is transferred to a PCP, both the PCP and the patient should be informed of the appropriate follow-up and management strategy. Re-referral for further oncology assessment may be considered, as needed, especially for patients who are receiving adjuvant endocrine therapy.					
NOT RECOMN	MENDED					
Routine blood	CBC testing is not recommended for routine breast cancer surveillance.					
tests	Automated chemistry studies are not recommended for routine breast cancer surveillance.					
Imaging studies	Chest x-rays are not recommended for routine breast cancer surveillance.					
	Bone scans are not recommended for routine breast cancer surveillance.					
	Ultrasound of the liver is not recommended for routine breast cancer surveillance.					
	CT scanning is not recommended for routine breast cancer surveillance.					
	FDG-PET scanning is not recommended for routine breast cancer surveillance.					
	Breast MRI is not recommended for routine breast cancer surveillance.					
Breast cancer tumor marker	The use of CA 15-3 or CA 27.29 is not recommended for routine surveillance of patients with breast cancer after primary therapy.					
testing	CEA testing is not recommended for routine surveillance of patients with breast cancer after primary therapy.					
Abbreviations: CBC, complete blood count: CEA, carcinoembryonic antigen: FDG-PET, [18F] fluorodeoxyglucose—positron emission tomography: MRI, magnetic resonance						

Abbreviations: CBC, complete blood count; CEA, carcinoembryonic antigen; FDG-PET, [18F] fluorodeoxyglucose-positron emission tomography; MRI, magnetic resonance imaging PCP, primary care physician.

<sup>\*</sup>All recommendations remain the same as those published in 2006. The Panel concluded that there was no new evidence that warranted changing any of the recommendations. The 2006 guideline provides a detailed discussion and rationale for the recommendations.

<sup>†</sup>Although the evidence is lacking, it seems likely that history as well as physical and breast exams may also be conducted by experienced non-physician providers (e.g., Nurse Practitioners, Physician Assistants) under the supervision of an experienced physician.

<sup>‡</sup>Expert consensus-based recommendations are available with criteria specific to patients with cancer (e.g., from the National Comprehensive Cancer Network [www.nccn.org

D. These recommendations includes includes include similar criteria as these from the U.S. Dreventing Services Task Force (USPSTE) as well as other criteria such as diagnosis of triple negative breast cancer, or a combination of breast cancer and other specific cancers.					
Mode of	Recommendation*				
Surveillance					

# Clinical Algorithm(s)

None provided

# Scope

# Disease/Condition(s)

Breast cancer

# Guideline Category

Counseling

Evaluation

Management

Risk Assessment

# Clinical Specialty

Family Practice

Internal Medicine

Medical Genetics

Nursing

Obstetrics and Gynecology

Oncology

Pathology

Radiation Oncology

Surgery

### **Intended Users**

Advanced Practice Nurses

Nurses

Patients

Physician Assistants

Physicians

## Guideline Objective(s)

- To provide recommendations on the follow-up and management of patients with breast cancer who have completed primary therapy with curative intent
- To update the 2006 guideline of the American Society of Clinical Oncology (ASCO) on breast cancer follow-up and management in the adjuvant setting

## **Target Population**

Women with breast cancer who have completed primary therapy with curative intent

### **Interventions and Practices Considered**

- 1. Clinical history
- 2. Physical examination
- 3. Patient education on symptoms of recurrence
- 4. Referral for genetic counseling
- 5. Breast self-examination (BSE)
- 6. Mammography
- 7. Coordination of care
- 8. Pelvic examination

Note: The following interventions were considered but not recommended for routine breast cancer surveillance:

Complete blood count (CBC) testing

Automated chemistry studies

Chest x-rays

Bone scans

Liver ultrasound

Computed tomography (CT) scanning

[<sup>18</sup>F]fluorodeoxyglucose-positron emissions tomography (FDG-PET) scanning

Breast magnetic resonance imaging (MRI)

Cancer antigen (CA) 15-3 or CA 27.29 testing

Carcinoembryonic antigen (CEA) testing

# Major Outcomes Considered

Overall survival

Disease-free survival

Quality of life

Toxicity reduction

Cost effectiveness

# Methodology

### Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

#### Literature Search Strategy

For the 2012 update, the Update Committee completed the review and analysis of data published since 2006. Computerized literature searches of MEDLINE and the Cochrane Collaboration Library were performed. The searches of the English-language literature published from March 1, 2006 to March 1, 2012 combined breast neoplasm terms with surveillance- and follow-up-related terms and MeSH headings. Results of the databases searches were supplemented with hand searching of the bibliographies of systematic reviews and selected seminal articles, and contributions from Update Committee members' personal files.

Inclusion and Exclusion Criteria

The literature search was limited to studies where the primary objective was the follow-up and management of patients with breast cancer who had completed primary therapy with curative intent. The outcomes of interest were disease-free survival, overall survival, health-related quality of life, reduced toxicity, and cost-effectiveness. The searches were limited to human-only studies and to randomized controlled trials, systematic reviews (with or without meta-analyses), and clinical practice guidelines. The literature review centered on randomized controlled trials and meta-analyses of data from randomized clinical trials.

For tumor markers, both randomized and non-randomized studies were eligible if they directly addressed clinical utility of one or more tumor markers (i.e., CA 15-3, CA 27.29, carcinoembryonic antigen [CEA]) by comparing outcomes of interest (i.e., disease-free survival, overall survival, health-related quality of life, or cost-effectiveness) for a group of patients monitored periodically with one or more of the listed tumor markers after completing primary therapy for operable breast cancer, with the same outcomes for a group of patients who are not monitored with any tumor marker. Treatment for recurrence in the monitored group could either be initiated based on marker levels alone, or based on imaging results after increased marker levels were detected, while treatment in the unmonitored group was initiated without knowledge of marker levels. Studies were excluded if they did not report at least one outcome of interest, did not compare outcomes for monitored and unmonitored patient groups, or only tested the performance characteristics (sensitivity, specificity, or positive and negative predictive values) of one-time marker test results (i.e., studies of analytic and/or clinical validity).

### Number of Source Documents

There were 14 new publications that met inclusion criteria: nine systematic reviews (three included meta-analyses) and five randomized controlled trials.

## Methods Used to Assess the Quality and Strength of the Evidence

Expert Consensus

# Rating Scheme for the Strength of the Evidence

Not applicable

# Methods Used to Analyze the Evidence

Review of Published Meta-Analyses

Systematic Review with Evidence Tables

# Description of the Methods Used to Analyze the Evidence

A comprehensive systematic review of the literature was conducted, and an Update Committee was convened to review the evidence and develop guideline recommendations.

Data Supplement Tables DS3 and DS4 (see the "Availability of Companion Documents" field) summarize the characteristics of the studies included in the literature review and analysis, along with their findings. There were no new randomized controlled trials (RCTs), systematic reviews, or meta-analyses identified in the review that specifically examined history or physical examination, breast self-examination, patient education

regarding symptoms of recurrence, or referral for genetic counseling. Additionally, there were no systematic reviews, meta-analyses, RCTs, or observational studies that met the inclusion criteria for breast cancer tumor marker testing.

### Methods Used to Formulate the Recommendations

**Expert Consensus** 

### Description of Methods Used to Formulate the Recommendations

In 1997, the American Society of Clinical Oncology (ASCO) published an evidence-based clinical practice guideline on breast cancer follow-up and management in asymptomatic patients after primary, curative therapy. ASCO guidelines are updated periodically by a subset of the original expert panel. The guideline was updated and published in 1999 and again in 2006. In March 2012, the Update Committee reviewed the results of a systematic review of the literature to determine whether the ASCO guideline recommendations needed additional updating.

This clinical practice guideline addresses three overarching clinical questions: (1) What guidance around follow-up and management should be available to women who have been previously treated for breast cancer? (2) What testing is recommended for the detection of breast cancer recurrence in the adjuvant setting after curative-intent primary therapy? (3) What is the optimal frequency of monitoring?

The Update Committee included academic and community practitioners, medical oncologists, a surgical oncologist, a radiation oncologist, hematologic oncologists, a gynecologic oncologist, a primary care physician, and a patient advocate. A Working Group of the Update Committee completed a review and analysis of evidence published between March 2006 and March 2012 to determine whether the recommendations needed to be updated. The Working Group drafted the guideline update and circulated it to the full Update Committee for review and approval.

### Rating Scheme for the Strength of the Recommendations

Not applicable

## Cost Analysis

Guideline developers reviewed published cost analyses.

One randomized controlled trial (RCT) performed a cost-benefit analysis of standard clinical follow-up compared with more intensive follow-up with additional imaging and laboratory tests and concluded that more-intensive follow-up was associated with higher costs without differences in early detection of relapses. However, the analytic methods were not described in the report, and therefore, the validity of this conclusion is difficult to ascertain.

### Method of Guideline Validation

Peer Review

# Description of Method of Guideline Validation

The Working Group drafted the guideline update and circulated it to the full Update Committee for review and approval. The American Society of Clinical Oncology (ASCO) Clinical Practice Guidelines Committee leadership reviewed and approved the final document.

# Evidence Supporting the Recommendations

# Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

In general, the evidence was limited to randomized controlled trials (RCTs), systematic reviews (with or without meta-analyses), and clinical practice guidelines.

# Benefits/Harms of Implementing the Guideline Recommendations

#### Potential Benefits

Appropriate follow-up and management of breast cancer in the adjuvant setting

### **Potential Harms**

Patients who receive tamoxifen therapy are at increased risk for developing endometrial cancer and should be advised to report any vaginal bleeding to their physicians.

# **Qualifying Statements**

## **Qualifying Statements**

The practice guideline is not intended to substitute for the independent professional judgment of the treating physician. Practice guidelines do not account for individual variation among patients and may not reflect the most recent evidence. This guideline does not recommend any particular product or course of medical treatment. Use of the practice guideline is voluntary.

# Implementation of the Guideline

## Description of Implementation Strategy

For information on the American Society for Clinical Oncology (ASCO) implementation strategy, please see the ASCO Web site

## **Implementation Tools**

Foreign Language Translations

Patient Resources

Resources

Slide Presentation

For information about availability, see the Availability of Companion Documents and Patient Resources fields below.

# Institute of Medicine (IOM) National Healthcare Quality Report Categories

#### IOM Care Need

Living with Illness

#### **IOM Domain**

Effectiveness

Patient-centeredness

Timeliness

# Identifying Information and Availability

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### Adaptation

Not applicable: The guideline was not adapted from another source.

#### Date Released

1997 May (revised 2013 Mar 1)

## Guideline Developer(s)

American Society of Clinical Oncology - Medical Specialty Society

# Source(s) of Funding

American Society of Clinical Oncology (ASCO)

### Guideline Committee

American Society of Clinical Oncology (ASCO) Clinical Guideline Update Committee

# Composition of Group That Authored the Guideline

Guideline Update Committee Members: Nancy E. Davidson, MD, (Co-Chair) University of Pittsburgh Cancer Institute and UPMC Cancer Center, Pittsburgh, PA; James L. Khatcheressian, MD, (Co-Chair) Virginia Cancer Institute, Richmond, VA; Elissa Bantug, MHS Johns Hopkins Medicine and Sidney Kimmel Comprehensive Cancer Center, Baltimore, MD; Laura J. Esserman, MD, MBA, Carol Franc Buck Breast Care Center and Helen Diller Family Comprehensive Cancer Center, University of California at San Francisco, San Francisco, CA; Eva Grunfeld, MD, DPhil, University of Toronto and Ontario Institute for Cancer Research, Toronto, Ontario, Canada; Francine Halberg, MD, Marin Cancer Institute, Greenbrae, CA; Alexander Hantel, MD, Edward Cancer Centers, Naperville, IL; N. Lynn Henry, MD, PhD, University of Michigan Comprehensive Cancer Center, Ann Arbor, MI; Hyman B. Muss, MD, Lineberger Comprehensive Cancer Center, University of North Carolina at Chapel Hill, Chapel Hill, NC; Thomas J. Smith, MD, Johns Hopkins Medicine and Sidney Kimmel Comprehensive Cancer Center, Baltimore,

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### Financial Disclosures/Conflicts of Interest

The Update Committee was assembled in accordance with the American Society of Clinical Oncology (ASCO) Conflicts of Interest Management Procedures for Clinical Practice Guidelines (summarized at http://chicago2013.asco.org/conflict-interest-policy ...).

Members of the Update Committee completed a disclosure form, which requires disclosure of financial and other interests that are relevant to the subject matter of the guideline, including relationships with commercial entities that are reasonably likely to experience direct regulatory or commercial impact as a result of promulgation of the guideline. Categories for disclosure include employment relationships, consulting arrangements, stock ownership, honoraria, research funding, and expert testimony. In accordance with these procedures, the majority of the members of the Update Committee did not disclose any such relationships.

Although all authors completed the disclosure declaration, the following author(s) and/or an author's immediate family member(s) indicated a financial or other interest that is relevant to the subject matter under consideration in this article. Certain relationships marked with a "U" are those for which no compensation was received; those relationships marked with a "C" were compensated. For a detailed description of the disclosure categories, or for more information about ASCO's conflict of interest policy, please refer to the Author Disclosure Declaration and the Disclosures of Potential Conflicts of Interest section in Information for Contributors.

Employment or Leadership Position: None Consultant or Advisory Role: N. Lynn Henry, GE Healthcare (C) Stock Ownership: None Honoraria: None Research Funding: None Expert Testimony: None Other Remuneration: None

#### **Guideline Status**

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American Society of Clinical Oncology. Recommended breast cancer surveillance guidelines. J Clin Oncol 1997 May;15(5):2149-56.

# Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the American Society of Clinical Oncology (ASCO) Web site

Print copies: Available from American Society of Clinical Oncology, Cancer Policy and Clinical Affairs, 1900 Duke Street, Suite 200, Alexandria, VA 22314; E-mail: guidelines@asco.org.

## Availability of Companion Documents

The following are available:

•	Breast cancer follow-up and management after primary treatment: American Society of Clinical Oncology clinical practice guideline update.
	Data supplement. Alexandria (VA): American Society of Clinical Oncology; 2012. 13 p. Electronic copies: Available in Portable Document
	Format (PDF) from the American Society of Clinical Oncology (ASCO) Web site
	Breact cancer follow, un and management after primary treatment: American Society of Clinical Opcology clinical practice guideline undate

Slide set. Alexandria (VA): American Society of Clinical Oncology; 2012. 23 p. Electronic copies: Available in Portable Document Format (PDF) from the ASCO Web site \_\_\_\_\_\_. Also available as a PowerPoint Slide Show from the ASCO Web site

#### **Patient Resources**

The following is available:

Patient guide. What to know: ASCO's guideline on follow-up care for breast car	ncer. 2012.	Available from th	e Cancer.Net	Web site
. Also available in Spanish at the Cancer.Net Web site				

Please note: This patient information is intended to provide health professionals with information to share with their patients to help them better understand their health and their diagnosed disorders. By providing access to this patient information, it is not the intention of NGC to provide specific medical advice for particular patients. Rather we urge patients and their representatives to review this material and then to consult with a licensed health professional for evaluation of treatment options suitable for them as well as for diagnosis and answers to their personal medical questions. This patient information has been derived and prepared from a guideline for health care professionals included on NGC by the authors or publishers of that original guideline. The patient information is not reviewed by NGC to establish whether or not it accurately reflects the original guideline's content.

### **NGC Status**

This NGC summary was completed by ECRI on February 26, 2013. It was verified by the guideline developer on December 1, 1998. This NGC summary was updated by ECRI on June 11, 1999, and November 22, 2006. The updated information was verified by the guideline developer on December 6, 2006. This NGC summary was updated by ECRI Institute on March 6, 2013.

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